

PG4715USw
Ser. No. 10/510,968

REMARKS

Claims 1-11 are pending in the application before entry of this amendment. Claims 12 and 14-25 have been withdrawn from consideration due to a restriction requirement. By way of this amendment, Claim 1 has been amended, and Claim 8 has been canceled.

Rejection under 35 USC 103

Claims 1-11 are rejected under 35 USC 103 as being obvious in view of Palmer in combination with Blair, et al. further in view of Roser, et al. More specifically, Palmer is cited as disclosing a combination of salmeterol, fluticasone propionate, and lactose excipient acting as a carrier. Blair is cited as disclosing derivatized carbohydrates as carrier particles. The Examiner combines the disclosure of Palmer and Blair in rejecting the pending claims.

Claim 1 has been amended to recite the particle size of a derivatized carbohydrate as 1 - 20 µm. The recitation was formerly presented in claim 8, now cancelled, and finds support on page 3, line 25 of the specification. The amended recitation distinguishes the derivatized carbohydrate from that of Blair at least on the basis of particle size.

The distinction in derivative carbohydrate particle size would not have been obvious to one of skill in the art because Applicants seek to use the derivatized carbohydrate particles in a different manner and for a different purpose than that disclosed by the references.

The Applicants seek to improve the stability performance of a salmeterol/fluticosone propionate blend (p.1, II.33-p.2, I.3; p.2, II.13-16), and prefer derivatized carbohydrate particles having a size range of 1 - 20 µm (p.3, I.25; p.11, full table) in order to achieve the desired improvement in stability (p.13 - p.14).

In contrast to Applicants use of particles for improved stability, the Blair reference discloses the use of derivatized carbohydrates as carrier materials. The carrier materials are said to have particle sizes of 30-300 µm (see p.2, II.16-17 and examples in Table 1 on page 5). Note, the 1 - 20 µm size range on page 4, line 7 of Blair refers to the therapeutic, not the derivatized carbohydrate particle. The Blair carrier particles are said to provide improved emitted dose uniformity (p.5, II. 24-25), and improvement of uniformity appears to be the main objective of the reference.

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One of ordinary skill in the art, in view of Blair, would not be led to experiment with derivatized carbohydrate particle sizes outside the range disclosed in the reference because a) the size of particles in inhaled powders are typically critical to desired performance, b) the reference teaches the use of particular particle sizes to obtain a particular result, namely dose uniformity, c) dose uniformity is distinct from Applicants objective of powder stability, and d) there is no suggestion that one of skill in the art seeking powder stability would be motivated to use particle size ranges designed for use in improving dose uniformity. Applicants, therefore, respectfully submit that the claims are not obvious in view of the combined references.

Provisional Obviousness-type Double Patenting Rejection

Claims 1-11 stand provisionally rejected on the grounds of non-statutory obviousness-type double patenting in view of application Ser. No. 10/511,042.

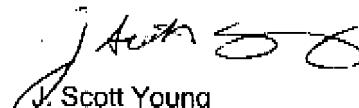
Applicants respectfully request that this rejection be deferred until this application or the reference application is found in condition for allowance.

Conclusion

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge any fees or credit any overpayment, particularly including any fees required under 37 CFR Sect 1.16 or 1.17, and any necessary extension of time fees, to deposit Account No. 07-1392.

Applicants respectfully submit that the instant application is in condition for allowance, which action is respectfully requested. The Examiner is invited to contact the undersigned at (919) 483-8160, to discuss this case, if desired.

Respectfully submitted,



J. Scott Young
Attorney for Applicants
Reg. No. 45,582

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GlaxoSmithKline Inc.
Five Moore Drive, PO Box 13398
Research Triangle Park, NC 27709
(919) 483-8160
fax: (919) 483-7988
Scott.S.Young@GSK.com